REMARKS

I. The Restriction Requirement

Applicant notes that the restriction requirement is maintained as to elected Group I, claims 1-28, directed to a pharmaceutical dosage form. Applicant gratefully confirms that the restriction requirement as between Groups II and III, process and apparatus for manufacturing holographic edible products such as pharmaceutical dosage forms, has been withdrawn. Further, applicant notes that newly submitted claims 63-72 focusing on a laser manufacturing process and product made using this process have been determined to be distinct from the elected Group I invention. Claims 29-72 are therefore withdrawn from consideration in this application.

Applicant, however, traverses the restriction requirement as applied against newly added claims 67 and 68. They depend from claim 1, directly or indirectly, and are directed to a pharmaceutical dosage form, the same as Group I. Thermoforming as described in the present application refers to the ability of a material to be affected by heat and pressure, or the heat of incident radiation, to form, or alter, a microrelief on its surface. Claims 67 and 68 are therefore specifics of the generic claim 1. Reconsideration of the restriction requirement as to claims 67 and 68 is respectfully requested.

II. The Amendments

The foregoing amendments in the Title reflect the subject matter of the elected Group I claims.

The foregoing amendments in claims 12, 21, 25 and 27 respond to the objections and Section 112, second paragraph, rejection of claims 12, 21 and 25-27. The

misspellings in claims 12, 21 and 27 are corrected. In claim 21, the phrase "is a high melting point wax that" is inserted after the word "material" in line 2 to define the subject matter of this claim with enhanced clarity. The specification at page 18, line 33, to page 19, line 1, identifies such a wax as a material so affecting the temperature response of the layer carrying the microrelief. Applicant believes that the meaning of claim 21 is clear and the Section 112 rejection is overcome.

Claim 25 is amended to introduce the word "modification" with reference to a design feature -- the shape or outer configuration of the core (introduced in claim 2, from which claims 4 and 25 depend) -- that produces a reduction in "twinning during pan-coating". Claims 26 and 27 dependent from claim 25 define this modification of the outer configuration with greater specificity. Also, in claim 27, ".6 radian" is amended to "0.6 radian". Such modifications in the shape or outer configuration are shown, for example, in Figs. 2-6C and 12A-12H. Applicant therefore believes that claims 26 and 27 now have a proper antecedent basis for "the modification" and otherwise overcome any Section 112 objections or rejections to claims 25-27.

III. The Invention

The present invention relates to a pharmaceutical dosage form. The form can be a strip (Fig. 10), a coated or plain tablet (e.g. Figs. 1-6C), a capsule (Fig. 7), a softgel, or any of the other forms delineated on at least page 2, first full paragraph, and page 10, lines 17 to page 11, line 9. A pharmaceutical dosage form is a dosage form that includes a pharmaceutically active ingredient, whether an ethical pharmaceutical or one sold over the counter.

These dosage form products must be edible; typically they are small enough to be ingested by swallowing or dissolving in the mouth. Known pharmaceutical dosage forms have characteristic shapes and colors to identify them. The shapes include a wide variety of curved and flat outer surfaces.

The pharmaceutical dosage forms of the invention, as defined by one or more of the pending claims, also satisfy various product characteristics of pharmaceutical dosage forms enumerated in the specification, e.g., beginning at page 2, line 14. They use FDA approved materials, are durable, and do not interfere with or degrade the efficacy of the active ingredient. They are also manufacturable in a commercially viable manner. They aid in brand identification, product differentiation, dye-less coloring, and the monitoring of storage conditions.

The present invention provides such a pharmaceutical dosage form that can create a holographic image or effect. To do so, the pharmaceutical dosage form as defined by all the pending claims includes in a layer of material characterized as thermoformable to receive and maintain a microrelief in that layer. Claims 1-6 specify that the resulting microrelief-bearing layer is also stable. The invention is further defined in claims 19-24 as a holographic dosage form where the display of the microrelief (corresponding to its stability) is controllable to provide information about the history and efficacy of the product. As will be detailed below, "pharmaceutical dosage form", "thermoformable" and "stable" are terms used in the pending claims that characterize the claimed product and are a marked, non-obvious departure from the prior art.

IV. The Differences Between the Claimed Invention and the Prior Art

Applicant respectfully traverses the rejection of claims 1-28 under 35 USC 102(b) as anticipated by Applicant's earlier U.S. Patent No. 4,668,523 ('523).

The '523 patent describes "products and methods for conferring holographic images to confections and other food products." (Col. 1, lines 7-8). The intent is to provide a "form of decoration which renders the particular food item more attractive and entertaining." (Col. 1, lines 15-16). The '523 Summary of the Invention at Col. 1, lines 32-42, and the discussion at Col. 2, lines 24-26, tell how this is done. Suitable organic polymer "gelling and/or coagulating agents" -- such as carbohydrates or amino acid polymers – for use in the '523 invention are ones that "may ... be used to produce the holographic edible element by methods described hereinbelow ...". The materials are further characterized in the '523 patent as ones that are: 1) dissolved, 2) "applied to a diffraction relief mold," 3) dried in the mold to transfer the diffraction gratings of the holographic images to the edible polymer, and 4) removed from the mold to produce a holographic "element." This element is a casting or "deposit" of a dehydrated solution on a mold. The holographic element is then used for confections and forms of decoration.

The materials of the '523 product are therefore ones suitable for applying, as by pouring, a solution of a material or materials into a mold, and then allowing them to "completely dry." (Col. 3, lines 61-62). The material(s) taught by the '523 patent are described at Col. 3, lines 62-68 as requiring varying times to dry, but twenty-four hours is

stated as "a good rule of thumb". The '523 holographic element with a diffraction pattern is therefore a dehydrated deposit material formed into a solid, in a mold.

The presently claimed pharmaceutical dosage form is nearly 180° different from the '523 decorated food product. The present claims define the present invention as a finished product that is 1) a dosage form, 2) that carries and delivers to a user a pharmaceutically active substance, 3) a layer of a material bearing a microrelief, where 4) that material is thermoformable (thermally reversible) to produce the microrelief , and, 5) as defined in claims 1-6 and 19-24, that microrelief on the surface of the layer is stable, and , as defined in claims 19-24, controllably stable.

A. The '523 patent does not teach a "pharmaceutical dosage form."

These claims terms are to be read on light of the specification. They are defined in the present specification, and used in the claims, to differentiate from the '523 products. The present specification, at page 1, line 27, begins by noting that while the '523 diffraction reliefs have provided "color and other visual effects on candies and other food products", they have not been used on dosage forms such as orally inserted pharmaceuticals. The reasons are stated in the specification on pages 2-4. "A major difference is that pharmaceutical dosage forms are non-deposited, that is, pharmaceuticals are not poured into a mold as a liquid to be formed, as with hard candy." (Page 2, lines 3-5). Pharmaceuticals "are small as compared to present commercial edible [holographic] products such as lollipops." (Page 3, lines 5-6). Pharmaceuticals "can have non-planar outer surfaces where it would be desirable to carry a holographic diffraction pattern." (Page 3, lines 6-7).

The Examiner argues that confections are defined as "sweetened mixtures of drugs". The '523 patent, however, does not use the term "drug", and it is clear from the entire thrust of the disclosure of the '523 patent that drugs are not the product that is described and claimed. If the cited passage is means to support that a confection is a pharmaceutical, this flies in the face of any ordinary meanings of these terms. The '523 patent says it is directed to "confections and other foodstuffs" (Col. 11, lines 9-10, emphasis supplied). The '523 patent continues by stating that it is directed to "decoration which renders the particular food item more attractive."

Page 10 of the present specification, and, indeed, the entire thrust of the specification herein, defines "pharmaceutical dosage form" as what is commonly understood as a medicine or supplement, not a food stuff or decoration. At page 10, line 18, the present specification defines "pharmaceutically active substance" as "**ethical** pharmaceuticals as well as orally administered, ingested products such a over-the-counter **medicines**." (Emphasis supplied.) The present specification then elaborates, "the term is used in its conventional sense to mean a pharmaceutically active compound or mixture of compounds for the treatment of a disease or condition," including "nutrient and diet supplements." Medicines are differently regulated than food, and concerns over the efficacy, manner of use, authenticity, storage, and interaction of medicines with other compounds are much different than for food products. Hence the present specification emphasizes that a workable pharmaceutical dosage form cannot react adversely with the active ingredient(s), whether in the manufacture of the dosage form or thereafter, and it must retain the efficacy of the active ingredients for the intended life of the product. The

'523 patent and the present invention deal with different products that have different purposes.

The '523 patent describes "holographic elements" that are substantially flat sheets that are thin enough to dry, albeit in hours, and flexible enough to de-mold without damaging the diffraction pattern, and not crack after being de-molded. More specifically, the dissolved materials of the '523 patent, e.g., sugars for lollipops, are a liquid "soup" held in a mold with a diffraction grating on its upper face. The "soup" runs to the lowest point in a mold. Flat molds control this liquid run and promote a uniformly thin liquid layer conducive to the dehydration and de-molding. The '523 patent at col. 3, line 68, to col. 4, line 2, also teaches that the de-molded sheet "is cut" to "yield the holographic element. "Flatness of the product is also an issue because formation of a holographic image or effect using microrelief on a curved surface is more difficult than using a flat surface, and the reconstruction of a holographic image or effect from a curved diffraction grating is more difficult than from one that is flat.

While the Examiner notes that lollipops are products mentioned in the '523 patent, and while conventional lollipops can be spherical or convexly curved, there is no teaching in the '523 patent of spherical or convex lollipops that can produce holographic images or effects. Nor is there any basis for reasoning backwards from the conventional lollipop to a food product described in the '523 patent.

As to manufacturability, thermoforming is described in the present specification (page 30, line 6) as taking a part of a second (0.3) to several seconds (3.0) for each dosage unit. The '523 deposit and dehydration method takes hours to form the

microrelief in a solid. There is no teaching or suggestion in the '523 patent that materials that receive a diffraction relief from a mold through drying a liquid solution for hours can, or should be, thermoformed to produce a stable microrelief in an already solid layer of these materials.

The '523 patent does not teach a dosage form, let alone a pharmaceutical dosage form. The '523 patent teaches away from the present invention because the '523 does not teach a product that solves the above-stated problems associated with pharmaceutical dosage forms.

B. The '523 patent does not teach a product having a layer of a material that is thermoformable to produce a microrelief

"Thermoformable" in the pending claims defines a layer of a product that is not a deposited layer, as taught by the '523 patent. The Examiner cites certain types of materials used in the '523 patent and the present application. The '523 patent teaches certain polymer "gelling and/or coagulating agents" that work to produce decorative holographic effects and images on foods where these materials are dissolved, applied to a mold, dehydrated, de-molded, and then processed for use, or used, as a foodstuff. There is no teaching or suggestion in the '523 patent that any class of materials, or any specific material, useful in a "deposit" process to produce a foodstuff with a microrelief can or should work successfully to bear a thermoformed microrelief as a layer of a pharmaceutical dosage form.

The '523 patent does not teach the thermoformable, microrelief-bearing layer of the present invention.

C. The '523 patent does not teach a product with a microrelief in a layer of material that is stable and/or controllably stable.

"Stable", appearing in certain of the pending claims, defines a material that can receive a microrelief by thermo-forming, and then, as specified in claims 1-6, retain it over the useful life of a pharmaceutical dosage form (be "stable"). Still other claims, e.g. Nos. 19-24, further define the stability to be controllable to control the corresponding display of information by the microrelief as to the history of the product. The controllability of changes in the visible images or effect, through a choice of materials and their relative proportions from the claimed layer, is described at least on page 11, line 16, through page 19, line 1, and later on page 19.

As to stability, the confections and other foodstuffs of the '523 invention in fact degrade due to mechanical stress, heat and humidity to a degree that is not acceptable for pharmaceutical products. This is because formed confections have a consistency that dissolves readily and is sufficiently flexible to be readily de-molded without changing the diffraction pattern. The microrelief presently claimed is characterized as thermoformed in a solid layer of material that is stable.

While the Examiner in part 11 of the Action contends that the materials disclosed in '523 patent include some that are "thermoformable and stable", this contention is neither expressly stated, or implied, by the '523 patent. The '523 patent teaches a dehydrated deposit layer formed from a solution with a diffraction grating. With respect to product life, the Examiner states that "[t]he response to temperature and humidity claimed by Applicant ... is inherent." In fact, confections made using the '523 invention

were sensitive to atmospherics and mechanical degradation. The holographic images and effects faded fairly quickly. It is not correct, as the Examiner contends, that the '523 patent discloses a microrelief with micron or less ridges and grooves that will react to atmospherics over time to be stable, and otherwise be suitable for use on a pharmaceutical dosage form.

As to stability due to moisture (humidity), what the '523 patent does teach is: 1) the use of malto-dextrose, "a dry corn-starch like material" that "will inhibit the pick up of ambient moisture" (Col. 2, lines 57-68); and 2) "to sandwich or coat an edible, transparent low hygroscopic humidity barrier between the holographic element and the food product on which the image is to be conferred," or "to leave a space between the food item and the diffraction grating ..." (Col. 3, lines 35-42). These solutions are not pertinent to the present application, and the claimed pharmaceutical dosage form.

V. The Dependent Claims Define Important and Patentable Features Not Found in the '523 Patent

Turning to the Examiner's rejections of certain dependent claims, applicant first notes that the reasons stated for the rejection of claims 4-6, 8, 13-17, and 25-28 do not overcome the deficiencies noted above of the principal '523 reference with respect to the independent claims 1 and 7.

Turning to specific ones of these dependent claims, claims 4-5 and 17 specify that the pharmaceutical dosage forms are "tablets" and "capsules," not foodstuffs such as candies. The '523 patent has no teaching regarding tablets or capsules, and therefore

cannot anticipate claims drawn to tablets and capsules. Claims 4-5 and 17 define patentable subject matter.

Claim 13, dependent via claims 11 and 12 from claim 7, specifies the relative portion by weight of the final dosage form having a core and an overlying layer of a material carrying a microrelief. The coating layer is stated as 0.25 to 5% of the total form, by weight. This weight ratio relates principally to the pan-coated tablet form of this invention, and indirectly to the thickness of the coating. It does not reflect, as suggested by the Examiner's comments, the nature of the constituent materials in the core or the layer, specifically, the percentage of malto-dextrin to organic polymers.

With respect to claim 14, dependent from claim 8 or 9, the passages from the '523 patent cited by the Examiner relate to a lamination of a sheet of hard candy, not a pharmaceutical dosage form. Moreover, the "pressing" quoted from the '523 patent is a way of "applying a **liquefied** organic polymer to a diffraction relief mold" (Col. 3, lines 46-47, emphasis supplied), not a thermoformed microrelief-bearing solid layer.

The product defined by claims 15 and 16 the specifies a bond between a solid outer layer and a core. Claim 15 specifies that the bond is a heat-fused or chemical bond. The cited passage from the '523 patent deals with dissolving an original polymer into a **liquid** solution that can be poured or otherwise applied to a mold to form a solid holographic element from this liquid solution. This cited passage has nothing to do with the nature of a bond of an outer layer to a core of a pharmaceutical dosage form.

Claim 25, dependent from claim 4, specifies that a feature of the invention is a core whose outer configuration has a modification that reduces twinning. The '523

patent does mention the "stickiness" of the food product. However, this stickiness relates to the product after it is manufactured; twinning is a problem that occurs during manufacture. To reduce stickiness post-manufacture, the '523 patent only teaches to increase the amount of malto-dextrin used if "sucrose, dextrose or fructose are added to the organic polymer." Applicant does not use or claim this solution to this very specific situation. Claim 25 teaches a product with a modified shape; the '523 patent has no such teaching or suggestion.

Claims 26-28 are directed to a product with a particular such modification in the outer shape of the core, namely, a reduction in the flat areas (claim 26) through convexly curved outer shapes (claim 27), or recesses (claim 28). First, the '523 patent neither teaches nor suggests any of these features of the claimed products. Second, while the '523 patent does describe the manufacture of lollipops, as discussed above, the '523 patent does not teach or suggest lollipops with microreliefs on curved faces, as specified in claim 27. In addition to the "pooling" problem noted above, if a curved mold is filled deeply enough to produce a suitably large diffraction grating, the dehydration will not be uniform, and demolding will be much more difficult, if possible at all. Also, the resulting diffraction pattern, if it can be formed and demolded, will be curved, which, under conventional thinking, is contraindicated for producing the holographic image or effect.

VI. Conclusion

Applicant has included with this Amendment a Petition for a two-month extension of time, to an including August 10, 2004, together with the appropriate fee.

In view of the foregoing amendments and remarks, applicant urges that the pending claims patentably distinguish over the art of record and that this application is otherwise in condition for allowance.

Respectfully submitted,

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Dated: August 10, 2004

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